

CLAIMS

1. A powdered formulation which is a freeze-dried mixture of a sensitive active material and an excipient containing:
- 5 from 0.01 preferably from 0.1, more preferably from 0.5 to 50 % by wt of the sensitive active material,
- from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of the excipient,
- wherein at least 0.1 % by wt of the mixture is an amorphous state.
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2. A formulation according to claim 1, in which from 0.1, preferably from 0.5, more preferably from 1 to 50 % by wt of the freeze-dried mixture is in an amorphous state.
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3. A formulation according to claim 1, containing:
- from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in amorphous state,
- from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of excipient in crystalline state,
- 20 0 - 5 % by wt of excipient in amorphous state.
4. A formulation according to claim 1, containing:
- from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt of sensitive active material in crystalline state,
- 25 from 50 to 99.89, preferably to 99.8, more preferably to 99.4 % by wt of excipient in crystalline state,
- 0.1 - 5 % by wt of excipient in amorphous state.
5. A formulation according to claim 1, containing
- 30 from 0.01, preferably from 0.1, more preferably from 0.5 to 25 % by wt of amorphous or crystalline state of sensitive active material,

from 75 to 99.49, preferably to 99.4, more preferably to 99 % by wt of crystalline state excipient,

0.5 - 5 % by wt of excipient in amorphous state

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6. A formulation according to any of claims 1 to 5 in which a saccharide is used to provide an excipient in amorphous state.

7. A formulation according to any one of claims 1 to 5 in which a
10 sugar alcohol is used to provide an excipient in crystalline state.

8. A formulation according to any one of the preceding claims which additionally contains from 0.1 to 10% by wt (preferably from 1 to 10% by wt) of additive/stabilizer.

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9. A formulation as defined in claim 8 wherein the additive/stabilizer is an antioxidant, a free radical scavenger and/or a Maillard reaction suppresser.

20 10. A formulation according to any one of the preceding claims wherein the sensitive active material is a labile organic and/or inorganic molecule, a biopolymer, a polypeptide, protein, enzyme, hormone, vitamin, antibiotic, polysaccharide, lipid, killed or live whole live cell.

25 11. A formulation according to claim 10 wherein the sensitive active material is a virus (including phage), bacterium, fungus and/or eukaryote.

12. A formulation according to any one of the preceding claims substantially as hereinbefore described.

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13. A formulation according to any one of the preceding claims for use in therapeutic treatment of a human or animal body.
14. A dosage form comprising a formulation according to any one of
5 the preceding claims.
15. A dosage form according to claim 14 which is a container which comprises the formulation according to any one of claims 1 to 13 or an article which has been formed from the formulation according to any one
10 of claims 1 to 13.
16. A dosage form according to claim 14 or claim 15 for use in therapeutic treatment of a human or animal body.
- 15 17. Use of a formulation according to any one of the claims 1 to 13 in the manufacture of a medicament for use in therapeutic treatment of a human or animal body.
18. Use of a dosage form according to any one of the claims 14 to 16
20 in the manufacture of a medicament for use in therapeutic treatment of a human or animal body.
19. A method of preparing a powdered formulation which comprises forming a mixed solution of sensitive active material and excipient(s)
25 containing:
from 0.01 preferably from 0.1, more preferably from 0.5 to 50 %
by wt of the sensitive active material,
from 50 to 99.99, preferably to 99.9, more preferably to 99.5 %
by wt of the excipient,
30 and freeze-drying the solution so that at least 0.1 % by wt of the freeze-dried blend is in an amorphous state.

20. A method according to claim 19 in which the active material freeze dries to a crystalline state and the mixed solution contains:
from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt
5 of sensitive active material in amorphous state,
from 50 to 99.99, preferably to 99.9, more preferably to 99.5 % by wt of
excipient in crystalline state,
0.1 - 5 % by wt of excipient which freeze dries to an amorphous state.
- 10 21. A method according to claim 19 in which the active material freeze dries to an amorphous state and the mixed solution contains:
from 0.01, preferably from 0.1, more preferably from 0.5 to 50 % by wt
of sensitive active material in crystalline state,
from 50 to 99.89, preferably to 99.8, more preferably to 99.4 % by wt of
15 excipient in crystalline state,
0 - 5 % by wt of excipient which freeze dries to an amorphous state.
22. A method according to claim 19, in which the mixed solution
contains:
20 from 0.01, preferably from 0.1, more preferably from 0.5 to 25 % by wt
of amorphous or crystalline state of sensitive active material,
from 75 to 99.49, preferably to 99.4, more preferably to 99 % by wt of
crystalline state excipient,
0.1 - 5 % by wt of excipient which freeze dries to an amorphous state.
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23. A method according to any of claims 19 to 22 in which a sugar is
used to provide an excipient in amorphous state.
24. A method according to any of claims 19 to 22 in which a sugar
30 alcohol is used to provide an excipient in crystalline state.

- 25: A method of medical treatment which method comprises supplying to a human or animal patient a therapeutically effective amount of a formulation according to any one of claims 1 to 13 or a therapeutically effective amount of a dosage form according to any one of claims 14 to
- 5 16.